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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,259	07/29/2003	Jih-Ru Hwu	BHT-3107-123	5436

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,259	HWU ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,8,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 7-8 and 15-16 are pending in this application.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-8 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (US 6,664,289).

Hansen teaches combating established microbial infection in animals such as humans by administering a composition that contains:

about 1.7 to 60,000 ppmw zinc gluconate or zinc bromide;

about 0.1 to 160,000 ppmw sodium bromide, sodium iodide or both;

about 55 to 75,000 ppmw of sodium chloride;

about 0.5 to 50,000 sodium hypochlorite; and

about 0.01 to 5 wt% glycerin.

See claim 15. See also broader disclosure on column 3, lines 4-57 and the remaining claims.

There are several differences between the claimed invention and the cited reference, which are discussed below.

Hansen does not explicitly disclose precisely the same exact weight ratios of ingredients A, B and C, as claimed by applicant, but such ratios are clearly disclosed and suggested by Hansen. The following table illustrates this position.

	(A)	(B)	(C)
Applicant's claims	$M^{+a}X^{-b}$, wherein M can be zinc and X can be gluconate or bromide	Ionic NX, wherein N can be sodium and X can be bromide or iodide	RY_z, wherein R can be sodium and Y can be chloride
Applicant's Ratio	1	10 to 50	1500 to 3000
Hansen's disclosure	Zn gluconate or Zn bromide	NaBr or NaI	NaCl
Hansen's Ratio	about 1.7 to 60,000	about 0.1 to 160,000	about 55 to 75,000

The patented claims by Hansen clearly show that microbial infection is controlled by Hansen's composition. Broad range of proportions is disclosed but the broad range is taught to be efficacious. It is the Examiner's position that from arriving at about 1.7 ppm zinc gluconate or bromide (hence inclusive of 2 ppm, 3 ppm, etc.), one having ordinary skill in the art would have been motivated to utilize varying amounts of sodium bromide or iodide and sodium chloride, as taught by Hansen, to control microbial infections. From the clearly recognizable and conveyed zinc compound (A) concentrations of, for example, 2 ppm, 3 ppm, etc., the relative quantity of sodium

chloride (C) would have been fairly suggested by the conventional delivery of pharmaceutical compositions as suitably formulated hypotonic, isotonic or hypertonic saline formulations. Multiple of 3000, for example, from 3 ppm zinc gluconate obtains a 9000 ppm saline solution, which happens to be physiologically isotonic saline. Further motivation to adjust NaBr or NaI concentrations to arrive at an effective microbial infection controlling agent, i.e. multiple of 10 to 50 of zinc gluconate or zinc bromide would have been well within the skill of the ordinary skilled artisan from the motivation to obtain routine optimization.

To be clear so that applicant does not misunderstand this rationale, it is the Examiner's position that Hansen's broad disclosure suggests applicant's claimed ratio of A:B:C. The above discussion is merely a further elaboration of that suggestion, i.e. how one of ordinary skill in the art would be further motivated to arrive at applicant's particular claimed ratio.

Method for producing the composition is suggested since the steps are mere mixing steps. Hansen's ingredients would have to be mixed to be in a single composition together. A spray form is expressly taught by Hansen (claim 15) as is the application to human beings (claim 15).

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because

every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
GROUP 1620